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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,953	07/31/2003	Bozidar Ferek-Petric	P8856.04	1782

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EXAMINER	
RAJAN, KAI	

ART UNIT	PAPER NUMBER
3769	

MAIL DATE	DELIVERY MODE
11/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/631,953	FEREK-PETRIC ET AL.	
	Examiner	Art Unit	
	KAI RAJAN	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 41* is/are pending in the application.

4a) Of the above claim(s) *7 - 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 6, 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges the reply filed December 12, 2007.

Note to Applicant Regarding Claim Interpretation: the terms "for," "adapted to," and "wherein" in the claim(s) may be interpreted as intended use. Intended use/functional language does not require that reference specifically teach the intended use of the element. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 6 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Nappholz et al. U.S. Patent No. 5,113,869.

1. An interactive remote drug dose and physiologic response monitoring system in a patient wherein at least one IMD is adapted to communicate with a drug delivery device, the monitoring system comprising:

a drug delivery device (Column 3 lines 38 – 68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25); and

an IMD in wireless communications with the drug delivery device (Column 3 lines 38 – 68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25),

wherein the IMD is implanted in a patient under a prescriptive regimen to take a drug from the drug delivery device and the IMD monitors the patient's physiological signs for compliance with a prescriptive regimen, and checks drug interaction in the patient (Column 3 lines 38 – 68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25).

2. The system of claim 1, wherein the delivery device is chosen from one of the following: a pill box, a transdermal patch, a IV, an inhaler, an oral medicament dispenser, a subcutaneous implant, a drug pump, or a transcutaneous application (Column 3 lines 38 – 68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25).

3. A drug delivery monitoring system comprising:

means for monitoring parameters of a drug delivery device (Column 3 lines 38 – 68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25);

means for communicating the monitored parameters with an IMD (Column 3 lines 38 – 68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25);

means for processing the monitored parameters (Column 3 lines 38 – 68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25);

means for controlling the drug delivery device based on the processing of the sensed parameters (Column 3 lines 38 – 68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25).

4. The system of claim 3, further comprising:

means for sensing physiological parameters through the IMD (Column 3 lines 38 – 68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25);

means for processing the sensed physiological parameters relative to a drug delivered by the drug delivery system (Column 3 lines 38 – 68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25); and

means for controlling the drug delivery system in response to the processing of the sensed physiological parameters (Column 3 lines 38 – 68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25).

5. The system of claim 3, further comprising means for controlling a therapy delivered by the IMD based upon the means for processing the monitored parameters (Column 3 lines 38 –

68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25).

6. An implantable medical device comprising:

a microprocessor for controlling cardiac therapy parameters (Column 3 lines 38 – 68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25);

a lead for delivering electrical stimulation to cardiac tissue (Column 3 lines 38 – 68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25); and

a telemetry unit for receiving information from a drug delivery device, the information identifying whether an expected drug therapy is delivered, wherein the microprocessor varies the cardiac therapy delivery through the lead based upon the information (Column 3 lines 38 – 68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25).

41. An interactive remote drug dose and physiologic response monitoring system in a patient wherein at least one IMD is adapted to communicate with a drug delivery device, the monitoring system comprising:

a drug delivery device (Column 3 lines 38 – 68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25); and

an IMD in wireless communications with the drug delivery device, wherein the IMD is implanted in a patient under a prescriptive regimen to take a drug from the drug delivery device and the IMD monitors the administration of the drug by the drug delivery device for compliance

with a prescriptive regimen, and checks drug interaction in the patient (Column 3 lines 38 – 68, column 4 lines 1 – 16, column 4 lines 55 – 60, column 21 lines 44 – 68, column 22 lines 1 – 25).

Claims 3 – 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellinwood, Jr. U.S. Patent No. 4,146,029.

3. A drug delivery monitoring system comprising:

means for monitoring parameters of a drug delivery device (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10);

means for communicating the monitored parameters with an IMD (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10);

means for processing the monitored parameters (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10);

means for controlling the drug delivery device based on the processing of the sensed parameters (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10).

4. The system of claim 3, further comprising:

means for sensing physiological parameters through the IMD (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10);

means for processing the sensed physiological parameters relative to a drug delivered by the drug delivery system (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10); and

means for controlling the drug delivery system in response to the processing of the sensed physiological parameters (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10).

5. The system of claim 3, further comprising means for controlling a therapy delivered by the IMD based upon the means for processing the monitored parameters (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10).

6. An implantable medical device comprising:

a microprocessor for controlling cardiac therapy parameters (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10);

a lead for delivering electrical stimulation to cardiac tissue (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10); and

a telemetry unit for receiving information from a drug delivery device, the information identifying whether an expected drug therapy is delivered, wherein the microprocessor varies the cardiac therapy delivery through the lead based upon the information (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kai Rajan whose telephone number is (571)272-3077. The examiner can normally be reached on Monday - Friday 9:00AM to 4:00PM.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kai Rajan/
Examiner, Art Unit 3769

/Michael C. Astorino/
Primary Examiner, Art Unit 3769

November 3, 2008